

### **REMARKS**

Favorable reconsideration and allowance of the present application is respectfully requested.

Currently, claims 42-61, including independent claim 42, are pending in the present application. For instance, independent claim 42 is directed to a system for conducting a lateral flow assay to detect the presence or quantity of an analyte in a sample. The system comprises a lateral flow membrane strip comprising a detection zone, wherein the sample is capable of traversing through said membrane strip from a point of application to said detection zone. The system also comprises a reading device that comprises a housing, a light barrier structure, an electromagnetic radiation source, and a sensor. The light barrier structure comprises a top plate and a bottom plate, wherein the bottom plate is positioned adjacent to the exterior surface of the housing. A receiving port is defined between the top plate and bottom plate such that the lateral flow membrane strip is capable of insertion therein. The bottom plate also defines a region through which electromagnetic radiation from the source is capable of passing before contacting the lateral flow membrane strip. The region has a size that approximates the size of the detection zone (e.g., 1.8 times or less). Furthermore, the electromagnetic radiation source and sensor are positioned so that electromagnetic radiation emitted from the source is capable of being reflected from the lateral flow membrane strip to the sensor.

In the Office Action, independent claim 42 was rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,304,468 to Phillips, et al. Phillips, et al. is generally directed to a method for determining the presence of an analyte with an

enzyme substrate that results in the production of hydrogen peroxide. The method involves applying to a porous matrix a small amount of blood to saturate the matrix. Bound to the matrix are one or more reagents of a signal producing system that result in an initial change in the amount of reflectance of the matrix. The change in reflectance over a predetermined period of time is related to the amount of analyte in the sample. (Cols. 3-4). For instance, Fig. 1 of Phillips, et al. illustrates one embodiment of a strip 10 having a thin matrix pad 11 positioned at one end of a plastic holder 12. A hole 14 is made in the holder 12 in the area to which the matrix pad 11 is attached so that the test sample can be applied to one side of the pad and light reflected from the other side. (Col. 6, ll. 17-27). Figs. 3 and 4 likewise illustrate the specific scanning machine 60 used by Phillips, et al. to detect the analyte. As shown, the strip 10 is guided into a slot 50 of the machine 60 by moving a notch 15 against post 65. This aligns the hole 14 over a test center 80 that includes multiple LEDs 5.

Notwithstanding the contentions set forth in the Office Action, Applicants respectfully submit that Phillips, et al. fails to disclose one or more limitations of independent claim 42. For instance, independent claim 42 requires the use of a lateral flow membrane strip. As is well known in the art, "lateral flow" strips are defined by lateral movement of a test sample from the point of application, through the membrane strip, and to the detection zone. Lateral flow allows for heterogeneous separation of the analyte in a controllable and accurate manner. Phillips, et al. simply does not disclose such a lateral flow strip.

In addition, independent claim 42 also requires that the bottom plate of the light barrier structure is positioned adjacent to the exterior surface of the housing and that a

receiving port is defined between the top and bottom plates. Further, the bottom plate of the light barrier structure defines a region through which electromagnetic radiation from the source is capable of passing before contacting the lateral flow membrane strip. The region approximates the size of the detection zone. In the embodiment shown in Figs. 3-4, for instance, the bottom plate 56 and top plate 50 define a receiving port 53 through which the lateral flow membrane strip may be inserted. Upon insertion, light generated by an LED is capable of passing through an aperture 54 to contact the strip. Light reflected by the strip may also pass through the aperture 54. Due to the size of the aperture relative to the detection zone, the total area through which light is allowed to pass is minimized, thereby optimizing the signal to noise ratio. Phillips, et al. simply does not disclose such a structure. Thus, for at least the reasons set forth above, Applicants respectfully submit that independent claim 42 patentably defines over Phillips, et al.

In the Office Action, original claims 30 and 32 were also objected to under 35 U.S.C. §112, second paragraph. With respect to claim 30, the Office Action stated that that it was uncertain what is meant by "flexible felt material" as all materials are flexible to some extent and the composition of felt is not exact. Without acquiescing in this rejection, Applicants note that new claim 51 requires only that the light absorbing member comprises a flexible material. Applicants respectfully note that one of ordinary skill in the art would readily understand the meaning of "flexible" in this context. In addition, with respect to claim 32, the Office Action stated that the term "elongated" was uncertain. Again, Applicants respectfully submit that the term "elongated" is readily understood by those skilled in the art. Moreover, the term "elongated" is not necessarily

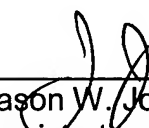
limited to elliptical shapes. For example, as shown in Fig. 5 of the present application, an elongated aperture 69 may be rectangular.

Claims 26-50 were also provisionally rejected in the Office Action under the judicially created doctrine of obviousness-type double patenting in view of copending applications 10/013,973, 10/026,415, and 10/084,763. In response, Applicants agree to submit terminal disclaimers, to the extent necessary to obviate this rejection, at such time that the present application is otherwise deemed in condition for allowance. As a final note, the Office Action appears to object to the number of references submitted in Applicants' Information Disclosure Statements. While Applicants certainly appreciate the Examiner's position, it is respectfully noted that the regulations impose a strict duty of disclosure on those associated with the filing and prosecution of a patent application. Applicants have simply attempted to comply with the duty of disclosure imposed by the PTO to the best of its ability. In no way whatsoever have Applicants attempted to cloak a relevant reference by including a long list of references. Applicants invite the Examiner to contact the undersigned should any question remain regarding any of the cited references.

It is believed that the present application is in complete condition for allowance and favorable action is respectfully requested. Examiner Alexander is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment. Please charge any fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,

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